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EXAMINER	
KRAMER, NICOLE R	

ART UNIT	PAPER NUMBER
3762	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/723,316	SPINELLI ET AL.	
	Examiner	Art Unit	
	Nicole R. Kramer	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 July 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-27 and 30-32 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-27, 36-37 of copending Application No. 10/236,578. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present application is merely broader than the ' 578 application (that is, the present application allows for such stimulation to treat more conditions). The more specific claims of the '578 application anticipate the broader claims of the present application, and thus the two claims are not

patentably distinct. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

3. Claims 7-8 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 7, 32, and 38 of copending Application No. 10/723,903. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would be obvious to one having ordinary skill in the art at the time of applicant's invention to modify the claimed method to stimulate the sacral nerves in addition to stimulating the pudendal nerve, since stimulation of sacral nerves for treating various pelvic floor disorders is well known in the art (for example, see U.S. Patent No. 4,607,639 which teaches a method for controlling bladder evacuation via electrical stimulation of sacral roots and/or pelvic floor nerves, including the pudendal nerve).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

4. Claims 7-8 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 7, 32, and 38 of copending Application No. 10/745,757. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would be obvious to one having

ordinary skill in the art at the time of applicant's invention to modify the claimed method to stimulate the left and right pudendal nerves, since stimulation of various pelvic floor nerves for treating various pelvic floor disorders is well known in the art (for example, see U.s. Patent No. 4,607,639 which teaches a method for controlling bladder evacuation via electrical stimulation of sacral roots and/or pelvic floor nerves, including the pudendal nerve).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

5. Claim 27 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/836,355. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would be obvious to one having ordinary skill in the art at the time of applicant's invention to modify the claimed method to stimulate the sacral nerves as an alternative or in addition to stimulating the pudendal nerve, since stimulation of sacral nerves for treating various pelvic floor disorders is well known in the art (for example, see U.S. Patent No. 4,607,639 which teaches a method for controlling bladder evacuation via electrical stimulation of sacral roots and/or pelvic floor nerves, including the pudendal nerve).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

6. Claim 27 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/836,840. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would be obvious to one having ordinary skill in the art at the time of applicant's invention to modify the claimed method to stimulate the sacral nerves as an alternative or in addition to stimulating the various claimed nerve locations, since stimulation of sacral nerves for treating various pelvic floor disorders is well known in the art (for example, see U.S. Patent No. 4,607,639 which teaches a method for controlling bladder evacuation via electrical stimulation of sacral roots and/or pelvic floor nerves, including the pudendal nerve).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

7. Claims 7-8 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 7 of copending Application No. 10/836,924. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would be obvious to one having ordinary skill in the art at the time of applicant's invention to modify the claimed method to stimulate the sacral nerves as an alternative or in addition to stimulating the various claimed nerve locations, since stimulation of sacral nerves for treating various pelvic floor disorders is well known in the art (for example, see U.S. Patent No. 4,607,639

which teaches a method for controlling bladder evacuation via electrical stimulation of sacral roots and/or pelvic floor nerves, including the pudendal nerve).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

8. Claims 7-8 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 7 of copending Application No. 10/836,927. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would be obvious to one having ordinary skill in the art at the time of applicant's invention to modify the claimed method to stimulate the sacral nerves as an alternative or in addition to stimulating the various claimed nerve locations, since stimulation of sacral nerves for treating various pelvic floor disorders is well known in the art (for example, see U.S. Patent No. 4,607,639 which teaches a method for controlling bladder evacuation via electrical stimulation of sacral roots and/or pelvic floor nerves, including the pudendal nerve).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

9. Claim 27 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/836,970. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would be obvious to one having ordinary skill in the

art at the time of applicant's invention to modify the claimed method to stimulate the pudendal nerve as an alternative or in addition to stimulating the various claimed nerve locations, since stimulation of pudendal nerves for treating various pelvic floor disorders is well known in the art (for example, see U.S. Patent No. 4,607,639 which teaches a method for controlling bladder evacuation via electrical stimulation of sacral roots and/or pelvic floor nerves, including the pudendal nerve).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

10. Claim 27 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/837,181. Although the conflicting claims are not identical, they are not patentably distinct from each other because the '181 application is merely broader than the present application (that, the '181 patent allows for stimulation at more locations than the present application). The more specific claim of the present application anticipates the broader claim of the '181 application, and thus the two claims are not patentably distinct. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

12. Claims 1-3, 6-9, and 11-32 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,941,171 ("Mann et al.").

Mann et al. discloses a method and system for treatment of incontinence, urgency, frequency, pelvic pain, and/or sexual dysfunction via electrical and/or drug infusion pulses delivered to the pudendal nerves and its branches (see, for example, col. 11, line 50 - col. 12, line 8). The stimulating electrodes and/or infusion catheters may be attached to or placed adjacent to any part of the pudendal nerve, including a portion of the pudendal canal and/or any of its distal branches, such as the dorsal nerve of the penis or clitoris (see col. 11, lines 10-15). Mann et al. discloses various stimulation sites, such as the urethral branch of the pudendal nerve, the inferior rectal branch of the pudendal nerve, somatic nerves innervating the rectum and/or colon, the dorsal nerve of the clitoris/penis, nerves innervating the urethra and/or detrusor muscle of the bladder, nerves innervating the vagina, Alcock's canal, and the perineum (see col. 11, line 50 - col. 12, line 40). The electrodes may be configured on or more leads

attached to an IPG, and the drug infusion system may be included as part of the electrical stimulator (see col. 12, lines 55-65).

With respect to claims 2 and 6, Mann et al. discloses that stimulator 100 may be programmed to produce either monopolar or bipolar electrical stimulation (see col. 21, lines 10-15). The stimulator case may be used as the indifferent electrode in monopolar stimulation.

With respect to claim 3, Mann et al. discloses that the leads preferably contains an array of collinear electrodes (see col. 21, lines 5-10). Examiner considers this description to anticipate "multiple electrodes disposed in an areal pattern on a planar or curved surface."

With respect to claim 7-8, Mann et al. discloses a second lead (70') attached to stimulator 100 (see Fig. 5 and associated text at col. 21, lines 1-5).

With respect to claim 9, Mann et al. discloses that high frequency neurostimulation typically has an inhibitory effect (see col. 22, lines 1-5). Treatment for pelvic pain necessarily includes masking or blocking pain signals.

With respect to claim 11, Mann et al. discloses that the leads (70) are preferably less than 5 mm in diameters, and more preferably less than 1.5 mm is diameter (see col. 21, lines 6-7).

With respect to claims 12-14, Mann et al. discloses that the length of the leads extend between 100 to 120 mm (see col. 13, line 67 - col. 14, line 12). If such leads contain 4 collinear electrodes as preferred (see col. 21, lines 6-10), such inter-electrode

distance and electrode surface area are necessarily within the claimed ranges of claims 12 and 13.

With respect to claim 15, stimulator 100 includes a processor and other electronic circuitry that allow it to generate electrical/infusion pulses that are applied to the patient (see col. 20, lines 59-63).

With respect to claims 16 and 18, the stimulator is activated and deactivated, programmed, and tested through a hand-held programmer 101, a clinician programming system 102, or a diagnostic system 103 (see col. 21, lines 17-36).

With respect to claim 17, Mann et al. discloses that stimulator 100 includes a rechargeable battery as a power source (see col. 20, lines 54-56).

With respect to claim 19, the medical leads are configured for percutaneous introduction and implantation within the patient.

With respect to claims 20-22, Mann et al. discloses that electrical stimulation parameters typically with include a frequency of 2-20 pps, a duration of 50-350 microseconds, and 1-5 volts (see col. 21, lines 48-65).

With respect to claim 23, Mann et al. discloses that multiple channels and/or multiple patterns of electrical and/or drug stimulation may be programmed by the clinician and controlled by the user in order to deal with complex dysfunctions (see col. 25, lines 50-65).

With respect to claim 26, Mann et al. discloses concomitantly delivering electrical stimulation and drug infusion (see col. 15, lines 20-24).

13. Claims 1-9, 11-20, 23, 25-27, and 32 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application Publication 2005/0209652 ("Whitehurst et al.").

Whitehurst et al. discloses a method and system for treatment of sexual dysfunction via application of a stimulating drug alone or in combination with electrical stimulation (see paragraph 0016). The system includes one or more control units (SCUs) that apply the electrical stimulation and/or one or more stimulating drugs to predetermined stimulation sites (see paragraph 0017). Electrodes are surgically implanted from an implantable pulse generator and one or more infusion outlets and/or catheters are surgically implanted to infuse drugs from an implantable pump (see paragraph 0017). The electrodes may be located at the distal portion of flexible leads (see Fig. 5 and associated text at paragraphs 0055 - 0061). Whitehurst et al. discloses that the electrodes and/or infusion outlets may be implanted adjacent any structure of the penis, including the prostatic plexus, the pudendal nerves, and the urethra (see paragraph 0100).

With respect to claims 2 and 6, Whitehurst et al. discloses that SCU 160 may be programmed to produce either monopolar or bipolar electrical stimulation (see paragraph 0061). The stimulator case may be used as the indifferent electrode in monopolar stimulation.

With respect to claim 3, Whitehurst et al. discloses that the leads preferably contain an array of collinear electrodes (see paragraph 0061). Examiner considers this

description to anticipate "multiple electrodes disposed in an areal pattern on a planar or curved surface."

With respect to claims 4-5, Whitehurst et al. discloses that the leads and/or catheters may have a barb as a fixation mechanism (see paragraph 0098).

With respect to claims 7-8, Whitehurst et al. discloses a second lead attached to SCU 160 (see Fig. 5 and paragraph 0060).

With respect to claim 9, Whitehurst et al. discloses that parameters such as high frequency stimulation may be chosen to have an inhibitory effect (see paragraph 0064).

With respect to claim 11, Whitehurst et al. discloses that the leads (70) are preferably less than 5 mm in diameter, and more preferably less than 1.5 mm in diameter (see paragraph 0061).

With respect to claims 12-14, Whitehurst et al. discloses that the length of the leads is not typically longer than about 150 mm (see paragraph 0055). If such leads contain 4 collinear electrodes as preferred (see 0060-0061), such inter-electrode distance and electrode surface area are necessarily within the claimed ranges of claims 10 and 11.

With respect to claim 15, SCU 160 includes a processor and other electronic circuitry that allow it to generate electrical/infusion pulses that are applied to the patient (see paragraph 0062).

With respect to claims 16 and 18, the stimulator is activated and deactivated, programmed, and tested through a hand-held programmer 200, a clinician programming system 202, or a diagnostic system 204 (see paragraph 0069).

With respect to claim 17, Whitehurst et al. discloses that stimulator 100 includes a rechargeable battery as a power source (see paragraph 0066).

With respect to claim 19, the medical leads are configured for percutaneous introduction and implantation within the patient.

With respect to claim 20, Whitehurst et al. discloses that electrical stimulation parameters may be chosen in various frequencies (see paragraph 0064).

With respect to claim 23, Whitehurst et al. discloses the stimulation parameters (such as pulse width, infusion rate, etc) may be infused by various rates of infusion (see paragraph 0046). Examiner considers "generates electrical pulses having varying spatial or temporal phases" to encompass such generating stimulation pulses of various rates of infusion, because the timing/temporal phase of the applied stimulation is varied. Further, Whitehurst et al. discloses that multiple channels and/or multiple patterns of electrical and/or drug stimulation may be programmed by the clinician and controlled by the user in order to deal with complex dysfunctions (see paragraph 0092).

With respect to claim 26, Whitehurst et al. discloses concomitantly delivering electrical stimulation and drug infusion (see paragraph 0063).

14. Claims 1, 2, 7-8, 14-29, and 32 stand rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,454,840 ("Krakovsky et al.").

Krakovsky et al. discloses an implanted device called a potency package that includes a battery 40, a programmable signal circuit 42, and a pulse generator 46 (see col. 3, lines 25-35). The potency package delivers electrical stimulation pulses (see col.

3, lines 35-45) in order to provide the patient with at least partial relief from erectile/sexual dysfunction. Further, Krakovsky et al. discloses the teachings of the invention may be used for urine incontinence correction during sexual intercourse (see col. 6, lines 40-46). The device includes a medical lead having an electrode, which connects with the pelvic splanchnic nerves (see col. 3, lines 49-55). In addition, a second electrode (49) extends from the device to the pudendal nerves (see col. 4, lines 5-19). Examiner considers the broadest reasonable interpretation of the term "adjacent" to be close, but not necessarily touching. Therefore, Examiner considers implantation of a medical lead adjacent to the pelvic splanchnic nerves and/or the pudendal nerves to necessarily result in a lead implanted "adjacent" to other nerves, such as the greater sciatic foramen, the lesser sciatic foramen, the ischial tuberosity, the sacro-tuberous ligament, the inferior rectal nerve, the perineal nerves, the scrotal nerves, Alcock's canal, and the penile dorsal nerve. As illustrated by Applicant's own Figures 3, 4B, 5, and 6, such nerve structures are close together but not necessarily touching.

For further description of application of Krakovsky et al. to claims 1, 2, 7-8, 14-29, and 32, please see the comments made in the office action dated 4/7/06.

Claim Rejections - 35 USC § 102/103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

16. Claims 1-2, 9, 14-19, 24, and 30-32 stand rejected under 35 U.S.C. 102(b) as being anticipated by, or in the alternative as being unpatentable over, "Neural Stimulation as a method of controlling prostatitis symptoms" (Chalfin), disclosed in 1999 Selected Abstracts from the American Urological Association annual meeting.

Chalfin discloses the use of sacral nerve stimulation for treatment of chronic prostatitis. The abstract provided from the 1999 the American Urological Association annual meeting discloses the method of claim 1, in that an implanted pulse generator and a medical lead are provided and implanted into the patient. Chaflin discloses that the medical lead is implanted adjacent to sensory nerves that supply the bladder, rectum, and pelvic floor. Chaflin discloses the sacral nerve as one stimulation site (i.e., see title and first paragraph), but does not explicitly disclose that these relevant sensory nerves may include, for example, a pudendal nerve or a sacral splanchnic nerve. Examiner considers the broadest reasonable interpretation of the term "adjacent" to be close, but not necessarily touching. Therefore, Examiner considers implantation of a medical lead adjacent to the sacral nerve to necessarily result in a lead implanted "adjacent" to other nerves, such as the pudendal nerve and the sacral splanchnic nerve because such nerve structures are close together but not necessarily touching.

In the alternative, Examiner notes that Chaflin discloses that the therapy works by applying chronic electrical stimulation to **sensory nerves that supply the bladder, rectum, and pelvis floor** (emphasis added). It is apparent from this teaching the Chaflin contemplates stimulation of other nerves besides the sacral nerve. Various

locations of claims 1, 30, and 32, including the pudendal nerve and sacral splanchnic nerve, are all nerves that supply the bladder, rectum and pelvis floor. It is known in the art to apply direct stimulation to these nerves in order to bypass the potential stimulation of unrelated nerve groups at the sacral roots (for example, see U.S. Patent No. 6,735,474 to Loeb et al. which teaches stimulation of pelvic floor nerves such as the pudendal nerve to treat chronic pelvic pain; col. 6, lines 17-24). It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the implanted medical lead of Chaflin to stimulate these other sensory nerves in order to more locally stimulate the nerve that is causing the patient pain (as taught by, for example, U.S. Patent No. 6,735,474 to Loeb et al.).

For further description of application of Chalfin to claims 1-2, 9, 14-19, 24, and 30-32, please see the comments made in the office action dated 4/7/06.

Claim Rejections - 35 USC § 103

17. Claims 4-5 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,941,171 ("Mann et al.").

As described above, Mann et al. discloses a method and system for treatment of incontinence, urgency, frequency, pelvic pain and/or sexual dysfunction via electrical and/or drug infusion pulses delivered to the pudendal nerves and its distal branches. The stimulating electrodes and/or infusion catheters may be attached to or placed adjacent to any part of the pudendal nerve (see col. 11, lines 10-15). The electrodes

may be configured on or more leads attached to an IPG, and the drug infusion system may be included as part of the electrical stimulator (see col. 12, lines 55-65).

With respect to claims 4-5, Mann et al. fails to explicitly disclose that the leads may include an active fixation mechanism disposed thereon, such as a suture sleeve, barb, or tissue in-growth mechanism. Examiner takes Official Notice that such active fixation mechanisms are well known in the art. It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the stimulation system of Mann et al. to utilize a fixation mechanism in order to securely implant the lead at the target nerve.

With respect to claim 10, Mann et al. does not explicitly disclose that a lead extension may be utilized. The common knowledge or well-known in the art statement made by the Examiner in the Office Action mailed 4/7/06 (that lead extensions are well known in the art; see page 18 of Office Action mailed 4/7/06) is taken to be admitted prior art because applicant failed to traverse the examiner's assertion of Official Notice (MPEP2144.03(C)). It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the stimulation system of Mann et al. to utilize a lead extension in order to modify the length of a lead to a desired length for implantation.

18. Claims 10, 21-22, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication 2005/0209652 ("Whitehurst et al.").

As described above, Whitehurst et al. discloses a method and system for treatment of sexual dysfunction via application of a stimulating drug alone or in combination with electrical stimulation (see paragraph 0016).

With respect to claim 10, Whitehurst et al. does not explicitly disclose that a lead extension may be utilized. The common knowledge or well-known in the art statement made by the Examiner in the Office Action mailed 4/7/06 (that lead extensions are well known in the art; see page 18 of Office Action mailed 4/7/06) is taken to be admitted prior art because applicant failed to traverse the examiner's assertion of Official Notice (MPEP2144.03(C)). It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the stimulation system of Whitehurst et al. to utilize a lead extension in order to modify the length of a lead to a desired length for implantation.

With respect to claims 21-22 and 24, Whitehurst et al. discloses that the SCU 160 allows for the electrical and/or drug stimulation parameters to be adjusted as needed for safe and efficacious treatment (see paragraph 0063), but fails to specifically disclose the capabilities of IPG. Such IPG capabilities are well known in the art, and it would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the stimulation system of Whitehurst et al. such that the IPG is capable of generating a wide range of stimulation parameters in order to effectively treat each individual's type and degree of sexual dysfunction.

19. Claims 4-8 and 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over "Neural Stimulation as a method of controlling prostatitis symptoms" (Chalfin) in view of U.S. Patent No. 6,055,456 ("Gerber").

As discussed above, Chalfin teaches implanted stimulation systems for stimulating portions of the sacral nerves for treatment of various ailments, such as prostatitis, chronic pelvic pain, or urinary incontinence disorders. Gerber teaches a prior art implantable medical lead for stimulation of the sacral nerves that simplifies the implant procedure (i.e., see col. 2, lines 30-40). It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the stimulation system of Chalfin to utilize the medical lead as taught by Gerber in order to simplify the implant procedure while still providing adequate electrical stimulation to the sacral nerve.

With respect to claims 4 and 5, Gerber teaches the lead has an active fixation device (see anchoring mechanism 50 and associated text).

With respect to claim 6, Gerber teaches that one or more electrodes of the lead can be configured to operate in conjunction with an electrically conductive portion of the pulse generator (i.e., see col. 4, line 65 - col. 5, line 5).

With respect to claims 7-8, Gerber teaches that implanting two medical leads for delivering electrical stimuli is known in the art (see col. 1, lines 35-55). It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the stimulation system of Chalfin to utilize the multiple leads in a stimulation

system as taught by Gerber in order to stimulate multiple target areas simultaneously or sequentially.

With respect to claim 10, Gerber does not explicitly disclose that a lead extension may be utilized. The common knowledge or well-known in the art statement made by the Examiner in the Office Action mailed 4/7/06 (that lead extensions are well known in the art; see page 18 of Office Action mailed 4/7/06) is taken to be admitted prior art because applicant failed to traverse the examiner's assertion of Official Notice (MPEP2144.03(C)). It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the stimulation system of Chalfin to utilize a lead extension in order to modify the length of a lead to a desired length for implantation.

With respect to claim 11, Gerber teaches a lead body having a diameter of .050 inches (or 1.27 mm), the lead body being made of polyurethane or silicone (col. 4, lines 5-12).

With respect to claim 12, Gerber teaches an inter-electrode distance of the first lead of about 16 mm (see col. 4, lines 30-55; when the first electrode contact 20 is 0.40 inches and the second electrode contact 40 starts 1 inch from the distal tip, the inter electrode distance is about 16 mm).

With respect to claim 13, the electrode surface area ranges between 1.0 square mm and 100 square mm (i.e., the embodiment of Fig. 1 discloses an electrode having .1 inch to 1.5 inches length and a diameter of preferably 0.5 inches. In an embodiment

where the length of electrode 20 is 1 inch, the surface area of the electrode is approximately 40 mm).

Response to Arguments

20. Applicant's arguments with respect to claims 1-32 have been considered but are moot in view of the new ground(s) of rejection.

21. In addition, Applicant's arguments filed 7/14/06 with respect to the rejections based on Chalfin and Krakovsky have been fully considered but they are not persuasive. Claims 1, 28, 30, and 32 require implantation of a medical lead "adjacent, around or in" various locations. Examiner considers the broadest reasonable interpretation of the term "adjacent" to be close, but not necessarily touching.

Therefore, with respect to Chalfin, Chaflin discloses that the medical lead is implanted adjacent to sensory nerves that supply the bladder, rectum, and pelvic floor. Chaflin discloses the sacral nerve as one stimulation site (i.e., see title and first paragraph). Examiner considers implantation of a medical lead adjacent to the sacral nerve to necessarily result in a lead implanted "adjacent" to other nerves, such as the pudendal nerve and the sacral splanchnic nerve because such nerve structures are close together but not necessarily touching.

Similarly, with respect to Krakovsky, the electrodes of the potency device at implanted at the pelvic splanchnic nerves (see col. 3, lines 49-55) and the pudendal nerves (see col. 4, lines 5-19). Examiner considers implantation of a medical lead

adjacent to the pelvic splanchnic nerves and/or the pudendal nerves to necessarily result in a lead implanted "adjacent" to other nerves, such as the greater sciatic foramen, the lesser sciatic foramen, the ischial tuberosity, the sacro-tuberous ligament, the inferior rectal nerve, the perineal nerves, the scrotal nerves, Alcock's canal, and the penile dorsal nerve. As illustrated by Applicant's own Figures 3, 4B, 5, and 6, such nerve structures are close together but not necessarily touching.

22. In addition, Applicant's arguments filed 7/14/06 with respect to the rejection of claim 22 based on Krakovsky has been fully considered but is not persuasive. Claim 22 requires the IPG to be capable of generating and delivering electrical pulses at various pulse widths. Krakovsky discloses that the parameters for electrical stimulation may be reprogrammed to change any of the parameters shown in Figure 12 (see col. 3, lines 42). The device described in Krakovsky is capable of generating pulse widths within the ranges of claim 22, and thus anticipates claim 22.

Conclusion

23. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

U.S. Patent Application Publication 2005/0261746 to Gross et al. teaches a device for treatment of a patient's urinary incontinence. The electrical stimulation may be delivered in the vicinity of the patient's urethra and/or bladder, as well as other muscles of the pelvic floor (see paragraph 0153).

24. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicole R. Kramer whose telephone number is 571-272-8792. The examiner can normally be reached on Monday through Friday, 8 a.m. to 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

NRK

8/4/06

George Manuel
Primary Examiner